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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

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04/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/619,649	DRMANAC, RADOJE	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 97 and 157-176 is/are pending in the application.
- 4a) Of the above claim(s) 176 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 97 and 157-175 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 20 February 2009 has been entered.

Status of the Claims

2. This action is in response to papers filed 20 February 2009 in which claims 166, 169-170 and 172-173 were amended. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 23 September 2008, not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection.

Claims 97, 157-175 are under prosecution.

Claim Objections

3. Applicant is advised that should claims 97 and 157-165 be found allowable, claims 166-175 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is

proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 166 has been amended to define an array of microarrays. Claim 97 is drawn to an array of microchips. Applicant points to the specification for support of the newly claimed "microarrays". The cited passages describe arrays of oligonucleotides on microchips. From this, Applicant is equating microarrays and microchips. It is acknowledged that "microarray" and "microchip" are both used currently to describe probes immobilized on a surface at high-density. Therefore, Claims 97 and 166 cover the same subject matter. The claim sets differ only in that Claim 97 defined the oligonucleotides as attached "at different locations". While Claim 166 does not include this recitation, oligonucleotides are inherently attached at different locations. By definition, attachment requires an attachment site. Hence, it is impossible to attach any two oligonucleotides to the exact same location. Therefore, despite a slight difference in wording, Claims 166-175 cover the same subject matter as Claims 97 and 157-165.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 97, 157-175 are rejected under 35 U.S.C. 103(a) as being unpatentable over Southern et al (Genomics, 1992, 13: 1008-1017) in view of Brigati (U.S. Patent No.

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4,777,020, issued 11 October 1988) or Augenlicht (U.S. Patent No. 4,981,783, issued 1 January 1991).

Regarding Claims 97, 157-158 and 166-168, Southern discloses a support comprising an array of four microchips, each having an array of oligonucleotide probes immobilized thereon (Fig. 3, figure legend, line 1).

Southern teaches each array is in one of four quadrants on the surface (Fig. 3). The four-quadrant arrangement is encompassed by the physical separation because a quadrant defines a physical location of the surface. Assignment of an array to a quadrant defines a boundary between quadrants, the boundary being the point of physical separation. While the reference specifically teaches that the arrays are physically separated, Southern does not specifically teach a physical barrier. However, physical and hydrophobic barriers separating hybridization regions were well known and routinely practiced in the art at the time the instant invention was made as taught by Brigati who teaches that the groove and hydrophobic barriers provide for comparative analysis of hybridization to the same probes to different samples and/or hybridization of different probes to the same sample (Column 9, line 63-Column 10, line 15).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the physical separation of Brigati to the multiple arrays of Southern. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success and for the benefit of comparative analysis of the multiple arrays to different samples as desired in the art (Brigati, Column 9, line 63-Column 10, line 15).

Furthermore, Augenlicht teaches multiple arrays on a support separated by a physical barrier i.e. spacing between membranes (Fig. 1) whereby side-by-side analysis and comparison of separately prepared arrays is provided (Column 7, lines 18-47). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the arrays of Southern by spatially separating the arrays as taught by Augenlicht. One of ordinary skill in the art would have been motivated to do so, with a reasonable expectation of success, for the benefit of providing side-by-side analysis and comparison of separately prepared arrays as desired in the art (Augenlicht, Column 7, lines 18-47).

Regarding Claims 159 and 169, Southern discloses the support wherein the microchips are arranged in multiple rows and columns (i.e. two rows and two columns, Fig. 3). And Brigati discloses the support comprising multiple rows and columns (e.g. 30 slide pairs providing 2 rows of 30 columns, Column 7, lines 44-45).

Regarding Claims 160 and 170, Southern discloses the support wherein the microchips are positioned for use with a multichannel pipette (Fig. 3). The arrays of Southern are arranged in two rows of two columns. While Southern does not teach use of a multichannel pipette, the courts have stated that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Southern teaches the structural elements of the claim and therefore, teaches the support of Claims 160 and 170.

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Regarding Claim 161 and 171, Brigati discloses the device wherein the device comprising assay ingredients e.g. labeled sample (Column 10, lines 8-15).

Regarding Claims 162 and 172, Southern teaches a 4 by 4 array but does not teach an 8 by 12 array. Brigati teaches the microchips wherein the nucleic acids are spotted in defined positions on the slides (Column 10, lines 8-15) but is silent regarding the an 8 x 12 format of spotted probes.

Furthermore, spotting probes in an 8 x 12 format was well known and routinely practiced in the art at the time the invention was made as taught by Augenlicht. Augenlicht further teach the format utilizes commercially available spotting pins that are useful for making replica arrays from multiwell cultures and produce precisely defined positions. (Column 6, lines 17-28 and Column 13, lines 55-60). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the 8 by 12 format of Augenlicht to the arrays of Southern and/or Brigati for the expected benefit of providing precisely defined and replicated regions as desired in the art (Augenlicht, Column 13, lines 55-60).

Regarding Claims 163 and 173, Southern discloses the support wherein the array of microchips comprises more than 256 probes i.e. each of the four microchips has 256 probes. Hence, the support of Claim 97 has more than 256 probes per array as claimed.

Regarding Claims 164 and 174, Southern discloses the support wherein the probes are between 4 and 9 bases (Fig. 3).

Regarding Claims 165 and 175, Southern discloses the support wherein the probes are synthesized on the support (page 1009, left column). Southern does not teach light-directed synthesis. However, the courts have stated that “even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113. Because determination of patentability is based on the product and because Southern teaches the product, the process of making the product as recited in the claim does not define the product over that of Southern.

New Grounds for Rejection

In the interest of expediting prosecution, new grounds for rejection are added.

Claims 97, 157-175 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drmanac et al (Electrophoresis, 1992, 13:566-573) and Hardy et al (U.S. Patent No. 4,681,853, issued 21 July 1987).

Regarding Claims 97, 157-158 and 166-168, Drmanac discloses a support comprising multiple microarrays (Fig. 4), each comprising an array of differing oligonucleotides immobilized thereon wherein the microarrays are separated from each other. The arrays illustrated in Fig. 4 clearly appear to be separated by a barrier, and

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the reference teaches that hybridization with different samples requires separation (page 571, last paragraph). The reference does not specifically teach physical barriers. However, physical barriers grooved and/or hydrophobic were well known in the hybridization art at the time the invention was made as taught by Hardy (Fig.1).

Hardy teaches a similar support comprising a plurality of arrays, each comprising differing oligonucleotides (Column 4, lines 17-56) wherein the arrays are separated by a physical groove and/or hydrophobic strip (Column 4, lines 39-56) whereby hazardous and/or costly materials are handled safely and efficiently (Column 4, lines 10-16).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the physical separation of Hardy to the multiple arrays of Drmanac. One of ordinary skill in the art would have been motivated to do so, with a reasonable expectation of success, for the expected benefit of providing for safe and efficient handling of hazardous and costly materials as desired in the art (Hardy, Column 4, lines 10-16).

Regarding Claims 159 and 169, Drmanac teaches the support wherein the microchips are arranged in multiple rows and columns (Fig. 4). And Hardy teaches the similar support comprising multiple rows and columns (Fig. 1).

Regarding Claims 160 and 170, Drmanac teaches the support wherein the microchips are "positioned" for use with a multichannel pipette (i.e. arrayed, Fig. 4). Hardy teaches the similar support wherein the microchips are "positioned" for use with a multichannel pipette (i.e. arrayed, Fig. 1).

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Regarding Claim 161 and 171, Drmanac teaches hybridization reagents (page 571). Hardy teaches the similar support and hybridization reagents (Column 11).

Regarding Claims 162 and 172, Drmanac teaches the arrays are arrayed in 8 by 12 format (paragraph spanning pages 569-570).

Regarding Claims 163 and 173, Drmanac teaches the support wherein the array of microchips comprises more than 256 probes (page 569-570).

Regarding Claims 164 and 174, Drmanac teaches the support wherein the probes of between 4 and 9 bases are spotted onto the arrays for hybridization (page 571).

Regarding Claims 165 and 175, Drmanac teaches the support of Claims 97 and 166 as discussed above. While the reference does not teach light-directed synthesis. However, the courts have stated that “even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113. Because determination of patentability is based on the product and because the combination of Drmanac and Hardy teach the product, the process of making the product as recited in the claim does not define the product over the prior art.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
Art Unit 1634

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